REMARKS

Claims 1-9, 11-46, 48, 50 and 55 are cancelled herein. Claims 47 and 49 are amended and new claims 58-79 are added herein. Claims 47, 49-51, and 56-79 are presently pending. The amended and new claims are supported by the specification and original claims so that their entry at this time is warranted. No new matter is being introduced. Specifically, the amendments to claims 47 and 49 are supported in the specification, for example at page 27, lines 30-32. New claims 58-59 and 60-61 are directed to plants or plant seeds produced according to the method of claim 47 or 49 respectively, as taught by the specification on pages 12-27. New claims 62-70 and 71-79 are also dependent on claims 47 and 49 respectively, listing specific first and second promoters and specific polypeptides encoded by the first and second exogene. New claims 62-79 are fully supported by the specification, for example at page 7, lines 1-32.

Claim 55 was objected to for the reasons set forth on page 2 of the Office Action. Claim 55 has been cancelled herein, so that the reasons for objection are no longer applicable.

Claim 55 was also rejected under 35 U.S.C. §112, first paragraph, as containing new subject matter which was not described in the specification for the reasons set forth on page 3 of the Office Action. As stated above, claim 55 has been cancelled and therefore Applicants respectfully request that this rejection be withdrawn.

Claims 47, 49 and 56-57 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement for the reasons set forth on pages 3-4 of the Office Action. Applicants traverse.

Applicants have amended claims 47 and 49 to require selection of a plant with the desired recombination event. The amendment does not narrow the scope of the claimed invention, but simply expressly sets forth an inherent step of Applicants' method. In addition, at the Examiner's suggestion, Applicants submit herein a clean copy of the PowerPoint presentation and a new declaration of Dr. Yesodi. The new declaration explains in more detail the data presented in the PowerPoint presentation and provides clear evidence that the presently claimed invention is fully enabled.

Before discussing the new declaration and the specific evidence of enablement, Applicants wish to correct a misunderstanding. On page 4 of the Office Action it states that "the instant specification fails to provide guidance for topical application of a recombinase protein to a plant, for getting the applied protein into the plant . . .." It was never the intention of Applicants to attempt to topically apply the recombinase protein to the

subject plant. Rather, as taught in the specification, at page 27, lines 27-32, and further explained in the PowerPoint presentation, the recombinase can be introduced into a plant containing the expression cassette, for example, by cross-fertilization (sexual crosses) with a plant known to carry an active recombinase or by use of transformation techniques, wherein expressible recombinase DNA is introduced into the expression cassette containing plants. As demonstrated herein, Applicants have successfully used both these methods (*See* PowerPoint presentation, Step 3).

One further clarification is needed. The Examiner states on page 4 of the Office Action that Gidoni et al. teaches "that germinal transmission of the recombined loci is a pre-requisite for its use in the instant method." As explained above, the recombinase is not introduced by topical application of the protein, but is present during the germinal stages of plant development. Therefore, Applicants see no contradiction between the teaching of Gidoni et al. and Applicants' use of recombinase in their method of generating plants having exogenic allelism.

The new declaration of Dr. Yesodi with PowerPoint presentation submitted herein provides further evidence of enablement. The PowerPoint presentation illustrates each step of Applicants' invention individually, with corresponding evidence of its successful implementation, which resulted in plants and plant seeds characterized by exogenic allelism. Figure 13 is a gDNA analysis of 16 plants produced by Applicants' presently claimed method. One hundred percent of the plants analyzed were characterized by exogenic allelism, *i.e.*, having both alleles in allelic relationship to one another. Applicants have provided sufficient teachings in the present application to enable one skilled in the art of plant genetic engineering to produce a plant or plant seed characterized by exogenic allelism.

Furthermore, Dr. Yesodi has declared as one skilled in the art that the presently claimed methods are enabled. Dr. Yesodi backs this declaration up by further providing a PowerPoint presentation giving a step by step explanation of the presently claimed method backed by results and actual production of plants having exogenic allelism. As evidenced by Dr. Yesodi presentation, one skilled in the art would be enabled, without undue experimentation, to use the presently claimed methods to generate plants having exogenic allelism.

For these reasons, Applicants respectfully request the rejection has been overcome and should be withdrawn.

Claims 47, 49-51 and 55-57 were rejected under 35 U.S.C. §112, first paragraph, for lack of written description for the reasons set forth on pages 4-6 of the Office Action.

The written description requirement is different from the enablement requirement. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Examiner has not met this burden.

The Examiner states on page 5 of the Office Action that "the specification only describes the constructs in Figs. 1 and 2 of the specification. Applicant does not describe other DNA molecules used by the methods or transformed in the plants and the structural features that distinguish all such nucleic acids from other nucleic acids." The examiner also states that "the structural features, *i.e.*, sequences, that distinguish all such plants from other plants are not provided."

Applicants' respectfully point out that these statements are not correct. The invention as presently claimed in claims 47 and 49 is directed to a method of generating exogenic allelism in a plant, not to the specific nucleotide or peptide sequences. These methods can be used to create exogenic allelism with numerous genes known in the art. Applicants fully describe each step of the methods and provide examples of exogenes that can be used. Furthermore, Applicants' teach that the "structural feature" that distinguishes the presently claimed methods and plants generated there from is the production of plants having the stable allelic placement of the exogenes in the plant genome. This is a structural feature that distinguishes their invention and demonstrates that they are in possession of the invention.

Applicants' invention is not dependent on the actual exogene chosen by the user. The user knows what exogenes he or she has introduced into the plant and using well

known molecular or biochemical techniques will be able to determine if the plant is carrying the exogenes. Furthermore, one skilled in the art clearly would be capable of determining whether a plant was expressing the desired phenotype indicative of the exogenes they had chosen.

Applicants never intended the method to only be used with the specific exogenes of Fig. 1 and 2. This is evidenced by their description on page 7 of the original specification. The method allows for the insertion of the exogene of choice in an allelic manner. On page 7 of the specification Applicants provide examples of exogenes that can be used, for example an RNA molecule, such as an antisense RNA molecule or a ribozyme; a gene that encodes proteins that assemble into hetero-oligomeric protein; a gene that encodes transactivators like RNA polymerase non-operable with eukaryotic promoters such as bacterial RNA polymerase or bacteriophage RNA polymerase: T7, T3, SP6; and a gene that encodes a cytotoxic or cytostatic polypeptide, such as pectate lyase, 1-3 β-glucanase, avidin, streptavidin, diphtheria Toxin A-chain (DTA), URF13, Indole acetic acid-lysine synthetase, CytA toxin and RNase-TI. Further, Applicants provide detailed examples as represented in Figs 1 and 2.

Section 112 does not require the Applicants list each and every DNA sequence that could be used in the claimed method, but rather it requires that Applicants provide sufficient detail that one skilled in the art can reasonably conclude that they were in possession of the invention. Here the number of examples present demonstrate that the Applicants had full possession of the presently claimed invention at the time of filing and the Examiner has not cited any evidence sufficient to contradict this.

The Examiner's concern regarding the phenotype to be expressed are resolved by the understanding, explained by Applicants at page 13, lines 16-24, that the expression of the chosen exogenes will determine the phenotype of the organism. Further, at page 20, lines 1-20, the Applicants explain that tissue specific promoters are well known in the art, such as anther-specific promoters, root-specific promoters, etc.

Applicants' presently claimed method was not designed to solely be used with the specific expression cassettes used in the illustrative examples. Rather, the presently claimed methods were designed so that one skilled in the art could use the exogenes of choice to generate plants characterized by exogenic allelism.

Applicants have met the written description requirement by describing each and every step of the presently claimed methods in the specification (see pages 7, 12-24), by providing specific examples of how to use the method (see Examples 1 and 2; Figures 1 and

2), and by providing detailed examples of specific implementations of the presently claimed method. And the Examiner has not cited any evidence or document that would cast doubt on the efficacy of the presently claimed method. Accordingly, one skilled in the art would reasonably conclude that the inventors had possession of the presently claimed methods of generating plants characterized by exogenic allelism and the plants produced by these methods.

In addition, the enclosed declaration of Dr. Yesodi supports this position in that she declares that, as one skilled in the art, having read the application as originally filed, she would reasonably conclude that the inventors had possession of the invention at the time of filing.

In view of the foregoing, Applicants respectfully request that this rejection be withdrawn.

Claims 47, 50 and 55-56 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,392,119 to Gutterson et al. (referred to hereafter as "Gutterson"). Applicants traverse.

As claims 50 and 55 have been cancelled herein, the rejection is only addressed as to claims 47 and 56. Applicants' invention as presently presented in these claims is directed to a method of generating exogenic allelism in a plant. Applicants' method has four steps. The third step of claim 47 is "selfing a plant resulting from step (b) and selecting a progeny devoid of recombinase having the expression cassette wherein the third segment has been excised." This step allows for the more reliable, predictable and reproducible production of exogenic allelism. As pointed out in the last response, by selecting out the gene encoding the recombinase, the plant with exogenic allelism produced thereby has a stable modified genome. This step is not taught or even mentioned in Gutterson.

In view of the fact that Gutterson fails to teach each element of Applicants' invention, Gutterson cannot anticipate Applicants' presently claimed invention. Applicants therefore request that the anticipation rejection based on Gutterson be withdrawn.

Claim 55 was rejected under 35 USC §102(b) as being anticipated by Fabijanski et al. As pointed out above, Claim 55 has now been cancelled.

In view of the foregoing, it is believed that the entire application is now in condition for allowance, early notice of which would be appreciated. Should any issues remain, a personal or telephonic interview is respectfully requested to discuss the same in order to expedite the allowance of all the claims in this application.

Respectfully submitted,

3/20/03
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